UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

JOSEPH HAVERL,	§	**CIVIL ACTION NO. _____**
	§	
PLAINTIFF,	§	
	§	
VS.	§	**COMPLAINT AND JURY DEMAND**
	§	
HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPAEDICS; OSARTIS GMBH F/K/A AAP BIOMATERIALS GMBH; AAP IMPLANTATE AG; and AAP IMPLANTS, INC.,	§	
	§	
DEFENDANTS.	§	

COMPLAINT

Plaintiff Joseph Haverl, by and through his undersigned counsel, hereby files this Complaint and alleges against Defendants as follows:

PARTIES, JURISDICTION, AND VENUE

1. At all times relevant to this Complaint, Joseph Haverl has been and continues to be a resident and citizen of Camp Hill, PA.

2. Defendant Howmedica Osteonics Corporation is a New Jersey corporation with its principal place of business located at 325 Corporate Boulevard, Mahwah, New Jersey 07430. Upon information and belief, Defendant Howmedica Osteonics is a wholly owned subsidiary of Defendant Stryker Corporation and does business as Stryker Orthopaedics. Defendant Howmedica Osteonics Corporation may be served through its agent of record, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

3. Defendant OSARTIS GMBH f/k/a aap Biomaterials GmbH is a German corporation with its principal place of business located at Lagerstraße 11-15, Dieburg, Germany 64807.

4. Defendant aap Implantate AG is a German corporation with its principal place of business located at Lorenzweg 5 12099, Berlin, Germany.

5. Defendant aap Implants, Inc. is the distribution company of aap Implantate AG for the North American market. Defendant aap Implants, Inc. may be served through its agent of record, Incorporating Services, Ltd., 3500 S. Dupont Highway, Dover, Delaware 19901.

6. At all relevant times, Defendants were the representatives, agents, employees, co-conspirators, servants, employees, partners, joint-venturers, franchisees, or alter egos of the other Defendants and were acting within the scope of such authority in such conspiracy, service, agency, employment, partnership, joint venture and/or franchise.

7. Each Defendant was involved, either directly or as described in the paragraph above, in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the Simplex HV bone cement, as well as monitoring and reporting adverse events.

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which Mr. Haverl resides.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Mr. Haverl's claims occurred, in part, in this District, and because Defendants conducted regular business in this District.

BACKGROUND

10. The knee is the largest joint in the human body, consisting of three individual bones: the shin bone (tibia), the thigh bone (femur), and the knee-cap (patella). The knee joint is lined with cartilage to protect the bones from rubbing against each other. This ensures that the joint surfaces can glide easily over one another. The human knee is a complicated joint which supports the entire body weight on four small surfaces through a variety of motions essential to everyday life. It is also the joint most susceptible to arthritis.

11. With the increases in lifespan, people have begun to suffer pain and disability from knee joint arthritis at significant rates. Knee replacement technology can provide a solution to the pain and restore basic function to those implanted. The knee replacement implants designed and approved in the 1990s met the goals of reducing pain and restoring function with low failure rates.

12. Total knee arthroplasty ("TKA"), also called total knee replacement ("TKR"), is a commonly performed orthopedic procedure. The surgery is designed to help relieve pain, to improve joint function, and to replace bones, cartilage and/or tissue that have been severely injured and/or worn down generally in people with severe knee degeneration due to arthritis, other disease or trauma. A TKA is ordinarily a successful orthopedic procedure with excellent clinical outcomes and survivorship.

13. In a total knee replacement surgery, sometimes referred to as "arthroplasty," physicians replace the joint surfaces and damaged bone and cartilage with artificial materials. The replacement redistributes weight and removes the tissue and/or bone causing inflammation, and

thus reduces pain while improving the joint's function. Replacement requires a mechanical connection between the bones and the implant components.

14. Bone cement, or epoxy, is used to attach components of the new artificial knee joint to the femur (thigh bone) and tibia (shin bone). Bone Cement includes a powder and a liquid that must be combined. Cement "viscosity" determines the handling and working properties of the cement. Bone cement may be divided into three types: low, medium, and high viscosity ("HV").

15. Defendants manufacture, market, and sell the "Simplex family of bone cements," including Simplex P and the Simplex HV bone cements.

16. Upon information and belief, Simplex P is a low or medium viscosity bone cement, also known as "non-HV." According to Stryker, as of 2008, Simplex P "emerged as the most used bone cement in the US" and "[n]o other bone cement has stronger survivorship than Simplex P."

17. Upon information and belief, prior to the release of Simplex HV, Defendants promoted their non-HV Simplex P bone cements as being stronger, safer, and more effective than HV bone cements manufactured and sold by other companies at that time.

18. In a 2008 brochure, Stryker explained the importance of viscosity by stating, "[t]he deeper cement penetrates into bone, the stronger the fixation and shear strength of the bond. HV cements cannot be pressurized into bone as well as medium viscosity cements."

19. Further, Stryker explained the concept of "creep" by stating, "[t]he physical behavior of bone cement has clinical significance in terms of mechanical fixation and loosening. Bone cements that creep too much may lead to *component shifting, loosening, and failure*." This section of the brochure was titled, "Creep Matters: Simplex [P] Creeps Less Than High Viscosity Cements."

20. Despite Stryker promoting that its non-HV cements were stronger, safer, and more effective than HV bone cements, Defendants devised a plan to design, manufacture, market, and sell their own HV bone cements.

21. Simplex HV bone cement, the product at issue, is a high viscosity cement. Simplex HV liquid when packed with Simplex HV cement powder forms the product Simplex HV Cement. Mixing the two separate components produces a ductile bone cement which, after hardening, fixes the implant and transfers stresses produced during movement to the bone.

22. Upon information and belief, Defendants received FDA clearance of the Simplex HV bone cement under the "510k" notification process. The basis for FDA clearance of Simplex HV bone cement was substantial similarity to prior bone cements. Consequently, Defendants received FDA 510(k) approval of the Simplex HV bone cement with only very limited, if any, testing of the new HV bone cement.

23. Defendants used the 510k approval process and claim that these HV bone cements are "substantially equivalent" to the non-HV cements that have been in use for decades. However, in fact—and as previously represented by Stryker—the HV cement was and is less effective, and more prone to component shifting, loosening, and failure than previously-approved bone cements.

24. According to the Orthopaedic Research Society, researchers found HV cement less effective than low- or medium-viscosity bone cement ("non-HV").

25. Further, according to a study in the *Journal of Arthroplasty*, researchers found that HV cement, including the Simplex HV bone cement, increases the risk of failure, even when used in combination with a previously well-performing implant.

26. The primary reason the Simplex HV bone cement fails is mechanical loosening. The mechanical loosening is caused by a failure of the bond between the tibial baseplate at the

implant-cement interface. Mechanical loosening means that the attachment between the artificial knee and the existing bone has become loose. Such loosening will eventually result in failure of the device. Mechanical loosening, as shown by recent studies, has occurred at a significantly increased rate in patients implanted with HV bone cement, including the Simplex HV bone cement.

27. A loose artificial knee generally causes pain and wearing away of the bone. It can severely restrict a patient's daily activities as it can involve a severe physical and emotional burden for the patient.

28. Once the pain becomes unbearable or the individual loses function of the knee, another operation, often called a "revision surgery," may be required to remove the knee implant and replace it with a new one.

29. Revision surgeries on a failed total knee due to loosening often require reconstruction of the severe bone loss.

30. The success rate of a revision surgery is much lower than that of the initial total knee replacement and the risks and complications are higher, including limitations in range of motion, the ability to walk, and even death.

31. Despite Defendants' knowledge of failures, Defendants continue to represent that its HV bone cements, including Simplex HV bone cement, are safe and effective. For instance, in 2014, Stryker promoted "Simplex HV" as "A New Level of Strength, Speed and Handling."

32. Although Stryker previously represented that HV bone cements are not as strong and effective because they do not penetrate the bone as well as Simplex P, Stryker suggests its internal test results show Simplex HV bone cement has a "statistically equivalent depth of intrusion compared to Simplex P." Further, Stryker states that "Simplex P and Simplex HV both achieve greater than the studies recommended 4mm depth of cement penetration into cancellous bone."

33. Defendants actively and aggressively marketed, promoted, and represented to doctors that Simplex HV could provide the speed and rapid mixing times of high-viscosity cement, while also marketing, promoting, and representing that Simplex HV was as strong, safe, and effective as non-HV cements.

34. Although Defendants knew about the high number of HV bone cement failures, including Simplex HV bone cement failures resulting in revision surgeries, Defendants failed to warn doctors, consumers and patients, and allowed, marketed, and promoted the defective design to continue to be implanted by unsuspecting surgeons into unsuspecting patients, including Mr. Haverl and his physicians.

CASE SPECIFIC FACTUAL ALLEGATIONS

35. On or about June 8, 2018, Joseph Haverl underwent a revision surgery from unicompartmental knee arthroplasty ("UKA") to total knee arthroplasty ("TKA"). Mr. Haverl's right-sided TKA was performed by Scott G.M. King, D.O. at UPMC Pinnacle in Harrisburg, PA.

36. In that procedure, Dr. King utilized Simplex High Viscosity ("HV") bone cement to cement all components in Mr. Haverl's right knee.

37. In the months following, Mr. Haverl experienced a "sharp and stabbing" pain in his right knee that was made "worse by movement and . . . made better by nothing."

38. On or about December 12, 2018, Dr. King decided a revision surgery was indicated after an injection of lidocaine into Mr. Haverl's knee significantly improved his pain.

39. On or about December 18, 2018, Mr. Haverl underwent a right revision TKA performed by Dr. King at UPMC Pinnacle in Harrisburg, PA. During the revision surgery, it became apparent that Mr. Haverl's pain was due to mechanical loosening of his tibial knee component. Specifically, the Stryker HV bone cement had completely debonded from the tibial

component. Dr. King stated in his Operative Report that "[w]e made sure that [the tibia] was fully exposed and then hit on the tibia with our blunt tool and it popped right out from the cement. *There was no cement whatsoever on the metal surface.* The cement was bonded very well to the bone."

40. As a result of the failed TKA due to debonding of the Stryker HV bone cement, Mr. Haverl has continued to experience pain and suffering and permanent physical impairment.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

41. Defendants failed to disclose a known defect and affirmatively misrepresented that the Simplex HV bone cement was safe for its intended use. Further, Defendants actively concealed the true risks associated with the use of the Simplex HV bone cement. Neither Plaintiff nor Plaintiff's physician had knowledge that Defendants were engaged in the wrongdoing alleged herein.

42. Because of Defendants' concealment of and misrepresentations regarding the true risks associated with the Simplex HV bone cement, Plaintiff could not have reasonably discovered Defendants' wrongdoing at any time prior to the commencement of this action.

43. Thus, because Defendants fraudulently concealed the defective nature of the Simplex HV bone cement and the risks associated with its use, the running of any statute of limitations has been tolled. Likewise, Defendants are estopped from relying on any statute of limitations.

44. Additionally, and alternatively, Plaintiff files this lawsuit within the applicable limitations period of first suspecting that the Simplex HV bone cement caused the appreciable harm sustained by Plaintiff. Plaintiff did not have actual or constructive knowledge of acts indicating to a reasonable person that Plaintiff was the victim of a tort. Plaintiff was unaware of

the facts upon which a cause of action rests until less than the applicable limitations period prior to the filing of this action. Plaintiff's lack of knowledge was not willful, negligent or unreasonable.

COUNT I
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

45. Mr. Haverl adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

46. At all times herein mentioned, Defendants are the researchers, designers, manufacturers, testers, advertisers, promoters, marketers, packagers, labelers, sellers and/or distributors of the Simplex HV bone cement, which is defective and unreasonably dangerous.

47. The Simplex HV bone cement is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. The Simplex HV bone cement is defective in design because it lacks efficacy, has a high failure rate, poses a greater likelihood of injury, is more dangerous than other available bone cements indicated for similar conditions and uses, and the utility of the Simplex HV bone cement does not outweigh its risks.

48. The defective condition of the Simplex HV bone cement rendered it unreasonably dangerous and/or not reasonably safe, and the Simplex HV bone cement was in this defective condition at the time it left the hands of Defendants. The Simplex HV bone cement was expected to and did reach Mr. Haverl and his physician without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

49. The Simplex HV bone cement was used for its intended purposes and the product was not materially altered or modified prior to its use.

50. The Simplex HV bone cement is defective in design because of its propensity to loosen and cause patients unnecessary pain, failure of the device and repeat surgical procedures, including revision surgery, resulting in additional bone loss and other complications.

51. The Simplex HV bone cement is defective in design because the increased risk for component shifting, loosening, and failure requiring revision surgery at an unreasonably greater rate than other non-HV bone cements.

52. At or before the time the Simplex HV bone cement was released on the market and/or sold to Mr. Haverl, Defendants could have designed the Simplex HV bone cement to make it less prone to debonding and loosening, and there was a practical, technically feasible safer alternative design that would have prevented the harm Mr. Haverl suffered without substantially impairing the function of the device.

53. Mr. Haverl was not able to discover, nor could he have discovered through the exercise of reasonable diligence, the defective nature of the Simplex HV bone cement. Further, in no way could Mr. Haverl have known that Defendants had designed, developed, and manufactured the Simplex HV bone cement in a way as to make the risk of harm or injury outweigh any therapeutic benefits.

54. The Simplex HV bone cement is and was being used in the Defendants' intended manner at the time it was surgically implanted into Mr. Haverl and during the time it remained in Mr. Haverl.

55. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use and breached this duty.

56. Defendants knew or should have known that the Simplex HV bone cement would be implanted in patients and that physicians and patients were relying on them to furnish a suitable

product. Further, Defendants knew or should have known that patients in whom the Simplex HV bone cement would be used, such as Mr. Haverl, could be and would be affected by the defective design and composition of the Simplex HV bone cement.

57. Defendants researched, designed, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Mr. Haverl, and Defendants are therefore strictly liable for the injuries sustained by Mr. Haverl.

58. As a direct and proximate result of Defendants' placement of the defective Simplex HV bone cement into the stream of commerce and Mr. Haverl's use of the defective Simplex HV bone cement as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants, Mr. Haverl suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Mr. Haverl demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT II
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

59. Mr. Haverl incorporates by reference all the forgoing language of this Complaint as if fully set forth herein and further states as follows.

60. At all times material hereto, Defendants were the manufacturers, designers, researchers, distributors, sellers, and/or suppliers of the Simplex HV bone cement and placed it in the stream of commerce in a condition which rendered it unreasonably dangerous due to its propensity to result in early debonding and failure of the device. The subject product was unreasonably dangerous in construction or composition.

61. Alternatively, the Simplex HV bone cement purchased and implanted in Mr. Haverl was defective because it varied from Defendants' intended design and contained unreasonably dangerous conditions.

62. As a direct and proximate result of the defective condition of the Simplex HV bone cement, Mr. Haverl suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Mr. Haverl demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

COUNT III
STRICT PRODUCTS LIABILITY- FAILURE TO WARN

63. Mr. Haverl adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

64. At all times material hereto, Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, marketed, sold to patients and/or introduced the Simplex HV bone cement into the stream of commerce knowing the cement would then be implanted in patients in need of a knee prosthesis. In the course of the same, Defendants directly advertised and/or marketed the product to health care professionals and consumers, including Mr. Haverl and Mr. Haverl's physicians, and therefore had a duty to warn of the risks associated with the use of the Simplex HV bone cement. Defendants breached this duty.

65. The Simplex HV bone cement was not accompanied by proper warnings and instructions to physicians and the public regarding potential adverse side effects associated with

the implantation of the Simplex HV bone cement and the comparative severity and duration of such adverse side effects.

66. The warnings, instructions, and information provided to the medical community and the public did not accurately reflect the symptoms, scope, or severity of potential side effects, specifically the risk of early mechanical loosening and debonding.

67. The Simplex HV bone cement was defective due to inadequate warnings, information, and instructions that failed to convey to physicians and the public accurate information about the scope and severity of potential side effects.

68. Had Defendants reasonably and properly provided adequate warnings, such warnings would have been heeded and no healthcare professional, including Mr. Haverl's physicians, would have used the Simplex HV bone cement, and no consumer, including Mr. Haverl, would have purchased and/or used the Simplex HV bone cement.

69. As a direct and proximate result of Defendants' conduct, Mr. Haverl has suffered and continues to suffer serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Mr. Haverl demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT IV
BREACH OF EXPRESS WARRANTY

70. Mr. Haverl adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

71. Defendants expressly warranted to Mr. Haverl by and through Defendants and/or their authorized agents or sales representatives, in publications, package inserts, the internet, and

other communications intended for physicians, patients, Mr. Haverl, and the general public, that the Simplex HV bone cement was safe, effective, fit and proper for its intended use.

72. For instance, Defendants expressly warranted that Simplex HV bone cement had the speed and fast-mixing times of other HV cements, while Simplex HV bone cement also had significantly equivalent strength and bone intrusion results as non-HV cements, including its own Simplex P bone cements.

73. The Simplex HV bone cement does not conform to those express representations because the Simplex HV bone cement is defective, is not safe, and has serious side effects.

74. Mr. Haverl and/or Mr. Haverl's physicians justifiably relied on Defendants' representations regarding the safety of the Simplex HV bone cement and Defendants' representations became part of the basis of the bargain.

75. As a direct and proximate result of Defendants' conduct, Mr. Haverl has suffered and continues to suffer serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Mr. Haverl demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT V
BREACH OF IMPLIED WARRANTY

76. Mr. Haverl adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

77. Defendants were the sellers of the Simplex HV bone cement and sold the Simplex HV bone cement to Mr. Haverl and/or Mr. Haverl's physician to be used in Mr. Haverl's knee implantation surgery.

78. When the Simplex HV bone cement was used by Mr. Haverl's physician, the product was being used for the ordinary purpose for which it was intended.

79. The Simplex HV bone cement sold to Mr. Haverl was not merchantable because it was not fit for its ordinary purpose to adequately bond knee implantation devices.

80. The Simplex HV bone cement would not pass without objection in the trade; is not of fair average quality; is not fit for its ordinary purposes for which the product is used; was not adequately contained, packaged and labeled; and fails to conform to the promises or affirmations of fact made on the container or label.

81. Defendants have been put on notice that the Simplex HV bone cement is not fit for its ordinary purpose.

82. Defendants breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in Mr. Haverl's body, which placed his health and safety at risk.

83. As a direct and proximate result of Defendants' conduct, Mr. Haverl has suffered and continues to suffer serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Mr. Haverl demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT VI
NEGLIGENCE

84. Mr. Haverl adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

85. Defendants had a duty to exercise reasonable and ordinary care in designing, researching, testing, manufacturing, marketing, supplying, promoting, distributing, approving, and selling the Simplex HV bone cement.

86. Defendants failed to exercise ordinary care in designing, researching, testing, manufacturing, marketing, supplying, promoting, distributing, approving, and selling of the Simplex HV bone cement in that Defendants knew or should have known that this product created a high risk of unreasonable, dangerous side effects, including the loosening and debonding at the tibial plate, thereby breaching their duty to consumers, including Mr. Haverl.

87. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Negligently designing the Simplex HV bone cement in a manner which was dangerous to those individuals who had the device surgically implanted;

(b) Designing, manufacturing, producing, creating and/or promoting the Simplex HV bone cement without adequately, sufficiently, or thoroughly testing it;

(c) Failing to adequately and correctly warn Mr. Haverl and his physicians, hospitals, and/or healthcare providers of the dangers of the Simplex HV bone cement;

(d) Failing to recall their dangerous and defective Simplex HV bone cement at the earliest date that it became known that the device was, in fact, dangerous and defective;

(e) Advertising and/or marketing the use of the Simplex HV bone cement despite the fact that Defendants knew or should have known of its defects;

(f) Representing that the Simplex HV bone cement was safe for its intended purpose when, in fact, it was unsafe;

(g) Manufacturing the Simplex HV bone cement in a manner which was dangerous to those individuals who had it implanted; and

(h) Under-reporting, underestimating, and/or downplaying the serious danger of the Simplex HV bone cement.

88. Upon information and belief, Defendants continued to market, manufacture, distribute and/or sell the Simplex HV bone cement to consumers, including Mr. Haverl, despite the fact that Defendants knew or should have known that the Simplex HV bone cement caused unreasonable, dangerous defects, including a defective tibial plate design leading to early debonding and early failures, when there were safer alternative designs available.

89. At all material times, Defendants knew of the defective nature of the Simplex HV bone cement as set forth herein, and continued to design, manufacture, market and sell it so as to maximize sales and profits at the expense of public health and safety, and as such Defendants' conduct exhibited a wanton and reckless disregard for human life.

90. As a direct and proximate result of Defendants' conduct, Mr. Haverl has suffered and continues to suffer serious and permanent non-economic and economic injuries.

WHEREFORE, Mr. Haverl demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT VII
NEGLIGENT MISREPRESENTATION

91. Mr. Haverl adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

92. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning the Simplex HV bone cement to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

93. Defendants disseminated to health care professionals and consumers — through published labels, marketing materials, and otherwise — information that misrepresented the properties and effects of the Simplex HV bone cement with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to implant, use and/or purchase the Simplex HV bone cement.

94. Defendants, as the designer, manufacturer, seller, promoter, and/or distributor of the Simplex HV bone cement knew or reasonably should have known that health care professionals and consumers of the Simplex HV bone cement rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of implanting, using and/or purchasing the Simplex HV bone cement.

95. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of the Simplex HV bone cement was accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

96. Defendants, as the designer, manufacturer, seller, promoter, and/or distributor of the Simplex HV bone cement, knew or reasonably should have known that health care professionals would use in reliance on the information disseminated by Defendants, and that the patients receiving implants of the Simplex HV bone cement, would be placed in peril of developing

serious injuries if the information disseminated by Defendants and relied upon was materially inaccurate, misleading, or otherwise false.

97. From the time the Simplex HV bone cement was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety of the Simplex HV bone cement. Defendant made material misrepresentations to Plaintiff, his healthcare professionals, the healthcare community, and the general public, including:

a. Stating that the Simplex HV bone cement had been tested and found to be safe, effective, fit and proper for its intended use;

b. Concealing, misrepresenting, and actively downplaying the severe risks of harm to users of the Simplex HV bone cement, when compared to technically feasible, safer alternative design; and

c. Misrepresenting the Simplex HV bone cement's risk of unreasonable, dangerous, adverse side effects.

98. Defendants made the foregoing representations without any reasonable ground for believing them to be true.

99. These representations were made directly by Defendants, their sales representatives and other authorized agents, and in publications and other written materials directed to healthcare professionals, medical patients, and the public.

100. Defendants made these representations with the intent to induce reliance thereon, and to encourage the implants, purchase, and use of the Simplex HV bone cement.

101. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff, the truth regarding Defendants' claims that the

Simplex HV bone cement had been tested and found to be safe, effective, fit and proper for its intended use.

102. The misrepresentations made by Defendants, in fact, were false and known by Defendants to be false at the time the misrepresentations were made.

103. Defendants failed to exercise ordinary care in making their representations concerning the Simplex HV bone cement and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the Simplex HV bone cement.

104. Defendants engaged in promotion of the Simplex HV bone cement in written marketing literature and in written product packaging. Defendants' promotion was undertaken by touting the safety and efficacy of the Simplex HV bone cement while concealing, misrepresenting, and actively downplaying the serious and severe risks of harm to users of the Simplex HV bone cement, when compared to technically feasible, safer alternative design. Defendants negligently misrepresented the Simplex HV bone cement's risk of unreasonable and dangerous adverse side effects.

105. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of the Simplex HV bone cement, including Plaintiff. Defendants had knowledge of the safety problems and suppressed this knowledge from the public. Defendants made conscious decisions not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

106. As a direct and proximate result of one or more of the above-stated negligent acts by Defendants, Mr. Haverl has suffered and continues to suffer serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Mr. Haverl demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT VIII
FRAUDULENT MISREPRESENTATION

107. Mr. Haverl adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

108. Defendants made fraudulent misrepresentations with respect to the Simplex HV bone cement in the following particulars:

a. Defendants represented through its labeling, advertising, promotions, marketing materials, presentations, publications, and regulatory submissions that the Simplex HV bone cement had been tested and found to be safe, effective, fit and proper for its intended use;

b. Upon information and belief, Defendants represented that the Simplex HV bone cement was safer than other alternative products; and

c. Defendants knew that its representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of the Simplex HV bone cement to Plaintiff, other consumers, Plaintiff's physicians, and the medical community.

109. The representations were made by the Defendants with the intent that doctors and patients, including Plaintiff and his physicians, rely upon them.

110. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, Plaintiff's physicians, and the medical community to induce and encourage the sale of the Simplex HV bone cement.

111. Plaintiff, his doctors, and others relied upon these representations.

112. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Mr. Haverl has suffered and continues to suffer serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Mr. Haverl demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT IX
FRAUDULENT CONCEALMENT

113. Mr. Haverl adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

114. Throughout the relevant time period, Defendants knew that the Simplex HV bone cement was defective and unreasonably unsafe for its intended purpose, and intentionally and willfully failed to disclose and/or suppressed information regarding the true nature of the risks of use of the Simplex HV bone cement.

115. Defendants fraudulently concealed information with respect to the Simplex HV bone cement in the following particulars:

a. Defendants represented through their labeling, advertising, promotions, marketing materials, presentations, publications, and regulatory submissions that the Simplex HV bone cement was safe and fraudulently withheld and concealed information about the severity of the substantial risks of using the Simplex HV bone cement;

b. Upon information and belief, Defendants represented that the Simplex HV bone cement was safer than other alternative products and fraudulently concealed information which demonstrated that the Simplex HV bone cement was not safer than alternative available design on the market;

c. Defendants were under a duty to Plaintiff to disclose and warn of the defective and dangerous nature of the Simplex HV bone cement.

d. Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangerous and unreasonable risks of the Simplex HV bone cement;

e. Defendant knowingly made false claims and omitted important information about the safety and quality of the Simplex HV bone cement in the documents and marketing materials Defendants provided to physicians and the public, including Plaintiff; and

f. Defendant fraudulently and affirmatively concealed the defective and dangerous nature of the Simplex HV bone cement from Plaintiff.

116. As the designers, manufacturers, sellers, promoters, and/or distributors of the Simplex HV bone cement, Defendants had unique knowledge and special expertise regarding the Simplex HV bone cement. This placed them in a position of superiority and influence over Plaintiff and his healthcare providers. As such, Plaintiff and his healthcare providers reasonably placed their trust and confidence in Defendants and in the information disseminated by Defendants.

117. The facts concealed or not disclosed by Defendants to Plaintiff and his physicians were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Simplex HV bone cement.

118. The concealment and/or non-disclosure of information by Defendants about the severity of the risks caused by the Simplex HV bone cement was intentional, and the representations made by Defendants were known by them to be false.

119. The concealment of information and the misrepresentations about the Simplex HV bone cement were made by Defendants with the intent that doctors and patients, including Plaintiff rely upon them so that Plaintiff would purchase the Simplex HV bone cement and his health care providers would implant and use the Simplex HV bone cement.

120. Plaintiff, his doctors, and others reasonably relied on Defendants' representations and were unaware of the substantial risk posed by the Simplex HV bone cement.

121. Had Defendants not concealed or suppressed information regarding the severity of the risks of the Simplex HV bone cement, Plaintiff's physician would not have implanted the Simplex HV bone cement and Plaintiff would not have purchased the Simplex HV bone cement.

122. Defendants, by concealment or other action, intentionally prevented Plaintiff and his health care professionals from acquiring material information regarding the lack of safety of the Simplex HV bone cement, thereby preventing Plaintiff from discovering the truth. As such, Defendants are liable for fraudulent concealment.

123. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Mr. Haverl has suffered and continues to suffer serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Mr. Haverl demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT X
VIOLATION OF PENNSYLVANIA'S UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAWS

124. Mr. Haverl adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

125. Plaintiff was implanted, purchased and used for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of consumer protection laws.

126. By reason of the conduct alleged herein, Defendants violated Pennsylvania's Unfair Trade Practices and Consumer Protection Law (UTPCPL), 73 P.S. 18 §201-1, et seq., by engaging fraudulent and deceptive conduct which created a likelihood of confusion and/or misunderstanding.

127. At all times relevant hereto, Defendants knowingly and intentionally induced Plaintiff and his physicians to use the Simplex HV bone cement through the use of false and/or misleading representations and statements.

128. The Simplex HV bone cement failed to perform as represented and, in fact, was unsafe.

129. Defendants induced Plaintiff and his physicians, through the use of false and/or misleading advertising, representations, and statements, as described above, to use and/or implant the Simplex HV bone cement, which Defendants manufactured and/or distributed and sold, all in violation of the UTPCPL, which proscribes, among other things:

a. Engaging in unfair trade practices as defined in the statute by making false and misleading oral and written statements that have the capacity, tendency, or effect of deceiving or misleading consumers;

b. Engaging in unfair trade practices as defined in the statute by making representations that its Simplex HV bone cement had an approval, characteristic, use, or benefit which it did not have, including but not limited to statements concerning the consequences of the use of the Simplex HV bone cement;

c. Engaging in unfair trade practices as defined in the statute by failing to state material facts, the omission of which deceived or tended to deceive, including but not limited to facts relating to the health consequences of the use of the Simplex HV bone cement; and

d. Engaging in unfair trade practices as defined in the statute through deception, fraud, misrepresentation, and knowing concealment, suppression, and omission of material facts with the intent that consumers rely upon the same in connection with the use and continued use of the Simplex HV bone cement.

130. As a foreseeable, direct and proximate result of Defendants' statutory violations, Plaintiff had the Simplex HV bone cement implanted, which he would not have had implanted had Defendants not issued false and/or misleading advertisements, representations, and statements.

131. Unfair methods of competition or deceptive acts or practices that were proscribed by law include the following employment of unlawful, unfair or fraudulent business acts or practices; unfair, deceptive, untrue or misleading advertising; and through omission and concealment, Defendant has misrepresented and continues to misrepresent that the Simplex HV bone cement (a) has characteristics, uses or benefits that it does not have; and, (b) is of a particular standard, quality or grade when it is of another.

132. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of the Simplex HV bone cement.

133. Defendants uniformly communicated that purported benefits of the Simplex HV bone cement while failing to disclose the serious and dangerous side effects related to the use of the Simplex HV bone cement and of the true state of its safety, its efficacy, and its usefulness. Defendants made these representations and omissions to physicians, the medical community at large, and to patients and consumers, including Plaintiff and Plaintiff's prescribing physicians.

134. Defendants' conduct in connection with the Simplex HV bone cement was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefit, costs, safety, efficacy and advantages of the Simplex HV bone cement.

135. But for Defendants' unlawful conduct, Plaintiff would not have purchased the Simplex HV bone cement. Instead, he would have purchased or used other safe and reliable treatments fit and safe for its intended purpose.

136. As a direct and proximate result of reliance upon Defendants' breaches of consumer protection laws, Mr. Haverl has suffered and continues to suffer serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

137. By reason of such violations and pursuant to the laws and regulations of this state, Plaintiff is entitled to recover all of the monies paid for the product; to be compensated for the cost of medical care arising out of the use of the Simplex HV bone cement; together with any and all actual damages recoverable under the law including, but not limited to, past medical expenses, past pain and suffering, disability, and emotional distress.

138. In addition, Plaintiff is entitled to recover fees and disbursements, including costs of investigation, reasonable attorneys' fees, and any other equitable relief as determined by this Court.

WHEREFORE, Mr. Haverl demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT XI
PUNITIVE DAMAGES

139. Defendants, through their agents, committed the acts alleged herein outrageously, maliciously, willfully, because of Defendants' evil motive or reckless indifference to the rights of others, including Plaintiff. Defendants failed to warn doctors, consumers and patients, and

allowed, marketed, and promoted the defective design to continue to be implanted by unsuspecting surgeons into unsuspecting patients, resulting in serious adverse health consequences, but despite this information continued to intentionally and falsely represent that using the Simplex HV bone cement was safe. Defendants downplayed the adverse effects of the Simplex HV bone cement, and misinformed and continued to promote the Simplex HV bone cement to the public. Defendants did so in order to preserve the lucrative and growing market they had carefully built with deception. The failure to inform doctors and their patients of material risks of the Simplex HV bone cement was intentional. Defendants acted with greed and other improper and evil motives amounting to malice, and in conscious disregard of Plaintiff's rights. The acts taken toward Plaintiff were carried out in a deliberate and intentional or grossly reckless manner with malice and without regard of the likelihood that Defendants' product would injure and damage Plaintiff and others. Plaintiff is entitled to recover punitive damages from Defendants in an amount according to proof.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Joseph Haverl prays for judgment against Defendants, individually and collectively, jointly and severally, as follows:

(a) Trial by jury;

(b) Judgment against Defendants for all compensatory and punitive damages allowable to Plaintiff;

(c) Judgment against Defendants for all other relief sought by Mr. Haverl under this Complaint;

(d) For reasonable attorneys' fees and costs;

(e) For pre-judgment interest; and

(f) For such further and other relief the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: December 16, 2020

/s/ Daniel R. Lapinski
Daniel R. Lapinski
MOTLEY RICE LLC
210 Lake Drive East, Suite 101
Cherry Hill, NJ 08002
Phone: (856) 382-4670
Fax: (856) 667-5133
Email: dlapinski@motleyrice.com

and

/s/ Brady D. Williams
Brady D. Williams (to be admitted *pro hac vice*)
Texas Bar No. 24072423
Ellen A. Presby (to be admitted *pro hac vice*)
Texas Bar No. 16249600
VAN WEY, PRESBY & WILLIAMS, PLLC
12720 Hillcrest Road, Suite 600
Dallas, Texas 75230
Tel: (214) 329-1350
Fax: (800) 582-1042
Email: courtfilings@vwpwlaw.com

COUNSEL FOR PLAINTIFF